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Date: February 11, 2004

TO Examiner Gollamudi Kishore

Fax Number. (571) 273-0598

Company: USPTO

Telephone:

Your Reference: 09/976,936

FROM: Deborah H. Yellin

Telephone: 703.838.6563

Our Reference: 033388-371

Sent By: Elizabeth K. Stenson

Number of Pages 7
Including Cover:

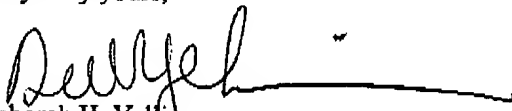
Message

Dear Examiner Kishore,

In accordance with our phone conversation yesterday, attached please find an Information Disclosure Statement Transmittal Letter, Information Disclosure Statement and Form PTO-1449 in connection with the above-identified application.

Should you have any questions, please do not hesitate to contact us.

Very truly yours,


Deborah H. Yellin
Reg. No. 45,904

Attorney's Docket No. 033388-371

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	Mailstop: Reissue
Eric MAYHEW et al.)	Group Art Unit: 1615
Application No.: 09/976,936)	Examiner: Gollamudi Kishore, Ph.D.
(Reissue of U.S. Patent No. 5,965,159))	Confirmation No.: 1802
Filed: October 11, 2001)	
For: ETHERLIPID-CONTAINING MULTIPLE)	
LIPID LIPOSOMES)	

FIRST INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56 and further to 37 C.F.R. § 1.178(b), the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

All of the listed documents were previously made of record in Application Serial No. 09/017,440 (now U.S. Patent No. 5,965,159), filed February 2, 1998, of which the present application is an application for reissue. In accordance with 37 C.F.R. § 1.98, a copy of each of the listed documents, except those documents which were previously made of record in the prior application, is enclosed.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date February 11, 2004By: Deborah H. Yellin
Registration No. 45,904

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(1/04)
VA 57017 1

Patent
Attorney Docket No. 033388-371

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Eric MAYHEW et al.

Group Art Unit: 1615

Application No.: 09/976,936

Examiner: Gollamudi Kishore, Ph.D.

Filing Date: October 11, 2001

Confirmation No.: 1802

Title: ETHERLIPID-CONTAINING MULTIPLE LIPID LIPOSOMES

FIRST
INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTERCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a FIRST Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge _____ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of _____ is enclosed for the fee due.


The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620Date: February 11, 2004

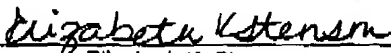
By


Deborah H. Yellin
Registration No. 45,904

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Facsimile Number: (571) 273-0598

Date of Transmission: February 11, 2004


Elizabeth K. Stenson

Typed Name:

BURNS DOANE
BURNS, DOANE, SWECKER & MATHIS LLP
INTELLECTUAL PROPERTY LAWFIRST
INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER

(1/04)

Patent
Attorney Docket No. 033388-371

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Eric MAYHEW et al.

Group Art Unit: 1615

Application No.: 09/976,936

Examiner: Gollamudi Kishore, Ph.D.

Filing Date: October 11, 2001

Confirmation No.: 1802

Title: ETHERLIPID-CONTAINING MULTIPLE LIPID LIPOSOMES

FIRST
INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTERCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a **FIRST** Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge _____ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of _____ is enclosed for the fee due.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

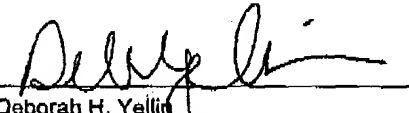
Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Alexandria, Virginia 22313-1404
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Date: February 11, 2004

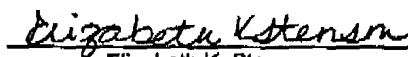
By


Deborah H. Yellin
Registration No. 45,904

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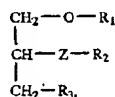

Elizabeth K. Stenson
Typed Name:BURNS DOANE
BURNS DOANE SWECKER & MATHIS LLP
INTELLECTUAL PROPERTY LAWFIRST
INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER

(1/04)

- Lewis and McElhane, "The Mesomorphic Phase Behavior of Lipid Bilayers," in *The Structure of Biological Membranes* (P. Yeagle, ed.), CRC Press, Inc. (1992), Boca Raton, Fl., pp. 73-155, at pp. 123-126.
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- Zeisig et al., *Anti-Cancer Drugs* 4: 57 (1993).

What is claimed is:

1. A liposome having a lipid bilayer which comprises: (a) a phosphatidylcholine; (b) a sterol; (c) a headgroup-derivatized lipid comprising a phosphatidylethanolamine linked at the ethanolamine group to a dicarboxylic acid; and, (d) an etherlipid having the formula:



wherein R_1 is Y_1Y_2 , Y_2 is CH_3 or CO_2H , Y_1 is $(\text{CH}_2)_{n1}$, $(\text{CH}=\text{CH})_{n2}(\text{CH}_2)_{n3}(\text{CH}=\text{CH})_{n4}(\text{CH}_2)_{n5}(\text{CH}=\text{CH})_{n6}(\text{CH}_2)_{n7}(\text{CH}=\text{CH})_{n8}(\text{CH}_2)_{n9}$, the sum of $n1+2n2+n3+2n4+n5+2n6+n7+2n8+n9$ is an integer of from 3 to 23, $n1$ is zero or an integer of from 1 to 23, $n3$ is zero or an integer of from 1 to 20, $n5$ is zero or an integer of from 1 to 17, $n7$ is zero or an integer of from 1 to 14, $n9$ is zero or an integer of from 1 to 11, and each of $n2$, $n4$, $n6$ and $n8$ is independently zero or 1;

wherein Z is oxygen or sulfur and R_2 is CH_3 ;

wherein R_3 is $-\text{O}-\text{P}(\text{O})_2-\text{O}-\text{CH}_2\text{CH}_2\text{N}(\text{CH}_3)_3$;

and wherein the phosphatidylethanolamine-dicarboxylic acid comprises from about 5 mole percent to about 20 mole percent of the lipid bilayer and the etherlipid comprises from greater than about 10 mole percent to less than about 30 mole percent of the lipid bilayer.

2. The liposome of claim 1 which is a unilamellar liposome having a diameter of from greater than about 50 nm to less than about 200 nm.

3. The liposome of claim 1, wherein the phosphatidylcholine is an unsaturated or partially unsaturated phosphatidylcholine.

4. The liposome of claim 3, wherein the phosphatidylcholine is dioleoyl phosphatidylcholine.

5. The liposome of claim 1, wherein the sterol is cholesterol.

6. The liposome of claim 1, wherein the headgroup derivatized lipid comprises a phosphatidylethanolamine selected from the group consisting of dipalmitoyl phosphatidylethanolamine, palmitoyl-oleoyl phosphatidylethanolamine and dioleoyl phosphatidylethanolamine.

7. The liposome of claim 6, wherein the headgroup derivatized lipid comprises dioleoyl phosphatidylethanolamine.

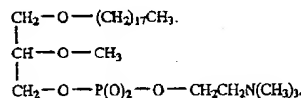
8. The liposome of claim 1, wherein the headgroup-derivatized lipid comprises a dicarboxylic acid selected from the group consisting of glutaric acid, sebacic acid, succinic acid and tartaric acid.

9. The liposome of claim 8, wherein the dicarboxylic acid is glutaric acid.

10. The liposome of claim 1, wherein the headgroup-derivatized lipid comprises dioleoyl phosphatidylethanolamine and glutaric acid.

11. The liposome of claim 1, wherein R_1 is $(\text{CH}_2)_{n1}\text{CH}_3$ and Z is O .

12. The liposome of claim 11, wherein the etherlipid is:



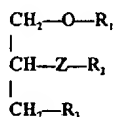
13. The liposome of claim 12, wherein the phosphatidylcholine is dioleoyl phosphatidylethanolamine, the sterol is cholesterol and the headgroup derivatized lipid comprises dioleoyl phosphatidylethanolamine and glutaric acid.

14. The liposome of claim 13, wherein the bilayer comprises about 20 mole percent of the etherlipid, about 10 mole percent of the headgroup-derivatized lipid, about 30 mole percent cholesterol and about 40 mole percent dioleoyl phosphatidylcholine.

15. The liposome of claim 1, comprising an additional bioactive agent.

16. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and the liposome of claim 1.

17. A liposome having a lipid bilayer which comprises: (a) a phosphatidylcholine; (b) a sterol; (c) a headgroup-derivatized lipid comprising a phosphatidylethanolamine linked at the ethanolamine group to a dicarboxylic acid; and, (d) an etherlipid having the formula:



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wherein R_1 is Y , Y_1 , Y_2 is CH_2 or CO_2H , Y_3 is $(CH_2)_{n1}$, $(CH=CH)_{n2}$, $(CH_2)_{n3}$, $(CH=CH)_{n4}$, $(CH_2)_{n5}$, $(CH=CH)_{n6}$, $(CH_2)_{n7}$, $(CH=CH)_{n8}$, the sum of $n1 + 2n2 + n3 + 2n4 + n5 + 2n6 + n7 + 2n8 + n9$ is an integer of from 3 to 23, $n1$ is zero or an integer of from 1 to 23, $n3$ is zero or an integer of from 1 to 20, $n5$ is zero or an integer of from 1 to 17, $n7$ is zero or an integer of from 1 to 14, $n9$ is zero or an integer of from 1 to 11, and each of $n2$, $n4$, $n6$ and $n8$ is independently zero or 1;

wherein Z is NH , $C(O)O$, or $HNC(O)$;

R_2 is CH_3 ;

R_3 is $-O-P(O)(-O-CH_2CH_2N(CH_3)_3)$; and

wherein the phosphatidylethanolamine-dicarboxylic acid comprises from about 5 mole percent to about 20 mole percent of the lipid bilayer and the etherlipid comprises from greater than about 10 mole percent to less than about 30 mole percent of the lipid bilayer.

18. The liposome of claim 17 which is a unilamellar liposome having a diameter of from greater than about 50 nm to less than about 200 nm.

19. The liposome of claim 17, wherein the phosphatidylcholine is an unsaturated or partially unsaturated phosphatidylcholine.

20. The liposome of claim 19, wherein the phosphatidylcholine is dioleoyl phosphatidylcholine.

21. The liposome of claim 17, wherein the sterol is cholesterol.

22. The liposome of claim 17, wherein the headgroup derivatized lipid comprises a phosphatidylethanolamine selected from the group consisting of dipalmitoyl phosphatidylethanolamine, palmitoyl-oleoyl phosphatidylethanolamine and dioleoyl phosphatidylethanolamine.

23. The liposome of claim 22, wherein the headgroup derivatized lipid comprises dioleoyl phosphatidylethanolamine.

24. The liposome of claim 17, wherein the headgroup-derivatized lipid comprises a dicarboxylic acid selected from the group consisting of glutaric acid, sebacic acid, succinic acid and tartaric acid.

25. The liposome of claim 24, wherein the dicarboxylic acid is glutaric acid.

26. The liposome of claim 17, wherein the headgroup-derivatized lipid comprises dioleoyl phosphatidylethanolamine and glutaric acid.

27. The liposome of claim 17, wherein R_1 is $(CH_2)_nCH_3$ and Z is $C(O)O$.

28. The liposome of claim 17, wherein R_1 is $(CH_2)_nCH_3$ and Z is NH .

29. The liposome of claim 17, wherein R_1 is $(CH_2)_nCH_3$ and Z is $HNC(O)$.

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30. The liposome of claim 17, comprising an additional bioactive agent.

31. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and the liposome of claim 17.